Atty Dkt. No.: SHIM-010 USSN: 09/889,611

# REMARKS UNDER 37 CFR § 1.111

# **Formal Matters**

Claims 8-13 are now pending in this application.

Original claims 1-7 have been cancelled and new claims 8-13 have been added to more particularly point out and distinctly claim the invention. The newly added claims are believed to be fully supported within the originally filed application.

New claims 8, 9, 10 and 11 are fully supported within originally pending now canceled claim 5. New claims 12 and 13 are supported within original claim 1 and within the sequences filed with the application which are now labeled as sequences with the SEQ ID NOS.: 60, 1, 19 and 20.

The nucleotide sequence of SEQ ID NO.:60, positions 3 to 42 (as shown in Figure 8), is the same as the nucleotide sequence of SEQ ID NO.:1, positions 1-40.

No new matter has been added.

#### **Objections to the Figures**

The figures and specifically Figures 1, 2, 7 and 8 was objected to due to the lack of Sequence Listing IDs. Applicants have attached hereto a new Figures 1, 2, 7 and 8 which includes sequence ID listings thereby overcoming the rejection.

#### **Certification Regarding Sequence Listing**

I hereby certify that the enclosed Sequence Listing is being submitted under 37 CFR §§ 1.821(c) and (e) in paper and computer readable form (Compact Disk labeled 'CRF').

As required by 37 CFR 1.821(f), I hereby state that the content of the paper and computer readable copy of the Sequence Listing, submitted in accordance with 37 C.F.R. §1.821(c) and (e) are the same. The Computer Readable Format (CRF), being submitted under 37 CFR §§ 1.52(e) and 1.824, is formatted on IBM-PC, the operating system compatibility is MS-Windows and the file listing is:

Seglist.txt 11.9 KB created December 12, 2003.

I hereby certify that the enclosed submission includes no new matter. The Sequence Listing was prepared with the software FASTSEQ, and conforms to the Patent Office guidelines. Applicant respectfully submits that the subject application is in adherence to 37 CFR §§ 1.821-1.825.

Atty Dkt. No.: SHIM-010 USSN: 09/889,611

## **Election/Restriction Requirement**

In response to the Restriction Requirement applicants elected Group I containing claims 1-5.

The new claims 8-13 are believed to be encompassed by the elected group. Specifically, claims 8-11 are directed to the elected method of screening claimed within previously pending now canceled claim 5 which included the portion of the DNA sequence identified as SEQ ID NO.:1 and 60. The nucleotide sequence of SEQ ID NO.:60, positions 3 to 42 (as shown in Figure 8), is the same as the nucleotide sequence of SEQ ID NO.:1, positions 1-40. New claims 11 and 12 relate to specific portions of SEQ ID NO.:60, 19 and 20 in terms of their patentability and are therefore believed to be encompassed by the elected group. Examination of all of the claims 8-13 would require a single search relating to specific portions of SEQ ID NO.:60 identified within the newly added claims. Accordingly, examination of the new claims 8-13 is respectfully requested.

## 35 U.S.C. §112 Rejection

Claims 1-5 were rejected under 35 U.S.C. §112, second paragraph. In support of the rejection specific phrases such as "a part thereof" was objected to as making the claims unclear. This phrase has been eliminated from the newly added claims 8-13 thereby rendering the rejection moot.

### Rejection under 35 U.S.C. §101

Claims 1 and 2 were rejected under 35 U.S.C. §101 as encompassing non statutory subject matter. A similar objection was raised with respect to claim 4.

The newly added claims 8-12 are clearly written in a manner so as to encompass only statutory subject matter. New claims 8-11 are directed to a method of screening which is clearly patentable subject matter. The new claims 12 and 13 refer to the "isolated" nucleic acid sequence thereby overcoming the objection with respect to claiming a product of nature.

#### Rejection under 35 U.S.C. §102

Claims 1-4 were rejected under 35 U.S.C. §102 as anticipated by Miyata et al. The rejection is traversed as applied and as it might be applied to the presently pending claims.

The rejection appeared to be based on the argument that Miyata et al. disclosed the entire sequence and that the claims as previously written in open format would encompass the entire sequence.

Atty Dkt. No.: SHIM-010 USSN: 09/889,611

The claims have been amended to eliminate such. Specifically, each of the claims is directed to a specific portion of SEQ ID NO.:60 and such specific portion is not disclosed within Miyata et al. Accordingly, Miyata et al. do not anticipate the presently pending claims and the rejection should be reconsidered and withdrawn.

#### Rejection under 35 U.S.C. §103

Claims 1-5 were rejected under 35 U.S.C. §103 as unpatentable over Miyata et al. (AA1) in view of Miyata et al. (AA2) and Chang US Patent 5,558,999. The rejection is traversed as applied and as it might be applied to the present pending claims.

To a large extent the rejection has been overcome or rendered moot by the claim amendments. Applicants specifically refer to Example 6 of the specification showing the presence of proteins that bind to the specific region of the SEQ ID NO.:60 which is pointed out within the currently pending claims. The binding portion that recognizes this region was specifically present in mesangial cells (see Example 6 on page 19, lines 18-21 and Figure 9). Accordingly, applicants have provided experimental data which indicates that the nucleotide sequence of a particular portion of SEQ ID NO.:60 which is specifically SEQ ID NO.:19 (also described as Probe A) and SEQ. ID NO.:20 (also described as Probe B) are regions which are essential for promoter activity. However, the cited references do not disclose any sequence information which is specific to the region encompassed by the currently pending claims. Accordingly, it is applicants position that the presently pending claims 8-13 are not taught by the cited references as taken alone or in combination with each other. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

#### **Summary**

Original claims 1-7 have been canceled and new claims 8-13 have been added. The specification and figures have been amended to include references to the required sequence ID listings and a computer readable form of the sequence is attached hereto. The newly added claims are all directed to a specific area of a specific sequence and are interrelated as such and believed to be encompassed by the elected group. The 35 U.S.C. §112 and 35 U.S.C. §101 rejections have been overcome by the cancellation of the original claims 1-7 and the addition of new claims 8-13 which do not include the terms and/or subject matter objected to. The 35 U.S.C. §102 rejection is overcome in that the specific sequence encompassed by the claims is not taught within the cited references. The 35 U.S.C. §103

Atty Dkt. No.: SHIM-010

USSN: 09/889,611

rejection is overcome in that the cited references as taken alone or in combination do not teach toward the criticality of the particular areas of sequences which are encompassed by the claims necessary to identify information with respect to promoter activity. In view of such all of the rejections are believed to be overcome.

In the event minor issues remain unresolved the Examiner is respectfully requested to contact the undersigned attorney at the indicated telephone number to arrange for an interview to expedite the disposition of this application.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number SHIM-010.

Respectfully submitted, BOZICEVIC, FIELD & FRANCIS LLP

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